Scientific Opinion on the substantiation of a health claim related to FRUIT UP® and a reduction of post-prandial blood glucose responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to FRUIT UP® and a reduction of post-prandial blood glucose responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from WILD-Valencia SAU, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to FRUIT UP® and a reduction of post-prandial blood glucose responses. The Panel considers that the food, FRUIT UP®, and the food (i.e. glucose, sucrose) that FRUIT UP® should replace in foods or beverages are both sufficiently characterised in relation to the claimed effect. A reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) is a beneficial physiological effect. In weighing the evidence, the Panel took into account that in the human intervention studies, from which conclusions could be drawn, FRUIT UP® decreased post-prandial blood glucose responses compared with glucose but not compared with sucrose, and that this effect may be explained by the partial replacement of glucose by fructose. The Panel concludes that a cause and effect relationship has not been established between the consumption of FRUIT UP® and a reduction of post-prandial glycaemic responses over and above the well-established effect of fructose on reducing post-prandial glycaemic responses when replacing glucose in foods.

KEY WORDS

FRUIT UP®, post-prandial blood glucose responses, health claims

[1] On request from the Competent Authority of Spain following an application by WILD-Valencia SAU, Question No EFSA-Q-2014-00405, adopted on 22 April 2015.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts, for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from WILD-Valencia SAU, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to FRUIT UP® and a reduction of post-prandial blood glucose responses.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.

The food that is the subject of the health claim is FRUIT UP®, a water extract from carob pods (*Ceratonia siliqua* L.) which, according to the applicant, should replace "high glycaemic carbohydrates" in foods or beverages in order to obtain the claimed effect (i.e. a reduction of post-prandial glycaemic responses). The Panel considers that the term "high-glycaemic carbohydrates" is not sufficiently defined. In the human intervention studies which were provided by the applicant in the original application, glucose and sucrose were used as the reference foods. The Panel considers that glucose and sucrose are the comparator foods. The Panel considers that the food, FRUIT UP®, which is the subject of the health claim, and the food (i.e. glucose, sucrose) which FRUIT UP® should replace in foods or beverages, are sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant is the "reduction of post-prandial blood glucose responses". The target population proposed by the applicant is: "individuals from the general population wishing to reduce their post-prandial glycaemic responses". The Panel considers that a reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) is a beneficial physiological effect.

The applicant submitted one published and 16 unpublished human intervention studies as being pertinent to the health claim.

One study assessed the effect of chronic consumption of FRUIT UP® on a long-term reduction in post-prandial blood glucose responses. Upon a request for clarification of the claimed effect and for further information on the study, the applicant provided clarification of the claimed effect and indicated that the study was no longer pertinent to the claim. At that time, the applicant also submitted one additional study which did not provide an analysis of post-prandial glycaemic responses. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The remaining 15 human studies assessed post-prandial blood glucose responses after the consumption of FRUIT UP® or FRUIT UP®-based drinks as compared with glucose (14 studies) or compared with sucrose (one study). In two of these studies, post-prandial insulinaemic responses were also assessed.

Compared with glucose, the consumption of FRUIT UP® and FRUIT UP®-based drinks significantly decreased post-prandial blood glucose responses. This effect was not observed when FRUIT UP® was compared with sucrose.

Post-prandial insulinaemic responses were shown not to be increased following consumption of FRUIT UP® compared with the reference foods, i.e. glucose and sucrose, respectively.

The Panel considers that the significantly lower post-prandial glycaemic responses observed with the consumption of FRUIT UP® and FRUIT UP®-based beverages, compared with pure glucose, could be explained by the partial replacement of glucose with fructose in FRUIT UP®. The Panel also notes that the only study which compared FRUIT UP® with similar amounts of sugars from sucrose

(contains a similar proportion of glucose and fructose as found in FRUIT UP®) did not show a significant effect of FRUIT UP® on post-prandial glycaemic responses (i.e. as compared with sucrose).

The Panel also notes that none of the studies which compared FRUIT UP® with glucose provides information on an independent effect of the so-claimed "bio-active" substances in FRUIT UP® on the reduction of post-prandial blood glucose responses (i.e. on an effect of FRUIT UP® over and above the effect which could be expected from the partial replacement of glucose with fructose).

In weighing the evidence, the Panel took into account that in the human intervention studies, from which conclusions could be drawn, FRUIT UP® decreased post-prandial blood glucose responses compared with glucose but not compared with sucrose, and that this effect may be explained by the partial replacement of glucose with fructose.

The Panel concludes that a cause and effect relationship has not been established between the consumption of FRUIT UP® and a reduction of post-prandial glycaemic responses over and above the well-established effect of fructose on reducing post-prandial glycaemic responses when replacing glucose in foods.

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BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 10/06/2014.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- On 31/07/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 16/09/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 29/09/2014.
- On 27/11/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the scientific evaluation was suspended on 10/12/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 19/12/2014, EFSA received the applicant's reply and the scientific evaluation was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 22/01/2015, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the scientific evaluation was suspended on 29/01/2015, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 11/02/2015, EFSA received the applicant's reply and the scientific evaluation was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 22/04/2015, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to FRUIT UP® and a reduction of post-prandial blood glucose responses.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: FRUIT UP® and a reduction of post-prandial blood glucose responses.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of FRUIT UP®, a positive assessment of its safety, nor a decision on whether FRUIT UP® is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address

WILD-Valencia SAU, Partida La Coma s/n, E-46740 Carcaixent, Spain.

The application includes a request for the protection of proprietary data, in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food that is the subject of the health claim is FRUIT UP®, which is a carbohydrate extract from carob pods (*Ceratonia siliqua* L.).

Health relationship as claimed by the applicant

According to the applicant, consumption of FRUIT UP® leads to a reduction in post-prandial blood glucose responses.

With regard to the proposed mechanism of action, the applicant claims that FRUIT UP® may exert its effect on post-prandial blood glucose responses because of its content of various "bio-active" substances, e.g. pinitol (6.77 ± 0.22 g/100 g), myo-inositol (0.72 ± 0.04 g/100 g), arabinoxylan (2.21 ± 0.34 g/100 g) and kestose (0.34 ± 0.11 g/100 g). In particular, pinitol and myo-inositol may, according to the applicant, improve insulin sensitivity (e.g. by inducing the translocation of glucose transporter type (GLUT) 4 within skeletal muscle cells), and may also improve markers of oxidative stress and inflammation. In addition, the applicant claims an inhibition of glucose absorption in the small intestine, partly because of the fibres (i.e. arabinoxylan and kestose) present in FRUIT UP®, but also because of a decrease in intestinal GLUT2 translocation.

Wording of the health claim as proposed by the applicant

In the original application, the applicant has proposed the following wording for the health claim: "FRUIT UP® induces a lower blood glucose rise than high glycaemic carbohydrates". Following a request for clarification of the claimed effect, the applicant proposed the following wording for the health claim: "FRUIT UP® reduces post-prandial blood glucose responses compared to high-glycaemic carbohydrates".

Specific conditions of use as proposed by the applicant

In the original application, the applicant proposed, as conditions of use for the health claim, a daily consumption of 60–70 g FRUIT UP® in two intakes (i.e. 30–35 g of FRUIT UP® twice daily). Following a request for clarification of the claimed effect, the applicant proposed the following conditions of use for the health claim: "High glycaemic carbohydrates should be replaced in foods or drinks by FRUIT UP® so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006. This regulation indicates that the reduction in high glycaemic carbohydrates should be at least 30 %".

The target population proposed by the applicant is individuals from the general population wishing to reduce their post-prandial glycaemic responses.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is FRUIT UP®, a water extract from carob pods (*Ceratonia siliqua* L.), which, according to the applicant, should replace "high glycaemic carbohydrates" in foods or beverages in order to obtain the claimed effect (i.e. a reduction of post-prandial glycaemic responses).

FRUIT UP® is extracted from the seedless fruits (i.e. pods) of the carob tree (*Ceratonia siliqua* L.) by water extraction, followed by blending with apple juice and white grape juice from concentrate. The mix of fruit juices is then further processed and concentrated to give a sugar content of 70 ± 1°Bx. Carob fruit (95.5–99.5 %) is the major source of soluble carbohydrates in FRUIT UP®. Detailed information on its composition was provided (as average ± SD per 100 g of FRUIT UP®), as follows: 34.8 ± 2.6 g sucrose, 11.0 ± 1.3 g glucose, 9.5 ± 1.0 g fructose, fibres (e.g. 2.2 ± 0.3 g arabinoxylan and 0.3 ± 0.1 g kestose) and polyols (e.g. 6.8 ± 0.2 g pinitol and 0.7 ± 0.04 g myo-inositol).

An overview of the manufacturing process, and batch-to-batch variability and stability data were provided.

Following a request for a definition of "high-glycaemic carbohydrates", which was proposed by the applicant as the reference food which ought to be replaced by FRUIT UP® in order to obtain the claimed effect, the applicant indicated that "high-glycaemic carbohydrates" refers to "any carbohydrate rapidly digested and absorbed in the small intestine that induces a high increase in plasma glucose level, as for example glucose, maltose, glucose syrup, maltodextrin, high digestible starches, and sucrose". In response to a further request for clarification of "high digestible starches" and the meaning of "high increase", the applicant indicated that "high digestible starches" correspond to "rapid digestible starches which are known to induce a rapid elevation of blood glucose", and that the term "high increase" means an "increase in blood glucose corresponding to at least 70 % of the glucose response".

The Panel considers that the term "high-glycaemic carbohydrates" is not sufficiently defined. The Panel notes that in the human intervention studies, which were provided by the applicant in the original application, glucose and sucrose were used as the reference foods. The Panel considers that glucose and sucrose are the comparator foods which ought to be replaced by FRUIT UP® in order to obtain the claimed effect.

The Panel considers that the food, FRUIT UP®, which is the subject of the health claim, and the food (i.e. glucose, sucrose) which FRUIT UP® should replace in foods or beverages, are sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is the "reduction of post-prandial blood glucose responses". The target population proposed by the applicant is: "individuals from the general population wishing to reduce their post-prandial glycaemic responses".

The conditions of use (i.e. "daily consumption of 60–70 g FRUIT UP® in two intakes"), as submitted in the original application, suggested a claim on long-term reduction of post-prandial blood glucose responses following consumption of carbohydrate-rich meals when FRUIT UP® is consumed for extended periods of time on a regular basis. Following a request for clarification of the claimed effect, the applicant indicated the wish to apply for a claim on the reduction of post-prandial blood glucose responses following the consumption of FRUIT UP® compared with a reference food, rather than long-term reduction of post-prandial blood glucose responses.

The elevation of blood glucose concentrations after the consumption of a food and/or a meal, i.e. post-prandial glycaemia, is a normal physiological response which varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Decreasing post-prandial glycaemic responses may, for example, be beneficial to individuals with impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is common in the general adult population.

The Panel considers that a reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed using the search term "pinitol" and setting a filter for "human". In addition, the company's archives were searched for pertinent studies. Studies were considered pertinent if they assessed the effect of FRUIT UP® on post-prandial glycaemia in healthy humans and were published in English or French. Studies conducted with "pinitol sources different from FRUIT UP®" and studies which were carried out in patients with type 2 diabetes (or any other disease which might have had an influence on blood glucose concentrations) were excluded.

The applicant submitted one published and 16 unpublished human intervention studies as being pertinent to the health claim.

One study (Bañuls et al., 2014, unpublished, claimed as proprietary by the applicant) assessed the effect of chronic consumption (i.e. twice a day for three months) of FRUIT UP® compared with a sucrose drink on a long-term reduction of post-prandial blood glucose responses. Upon a request for clarification of the claimed effect and for further information on the study, the applicant indicated the wish to apply for a claim on the reduction of post-prandial blood glucose responses following the consumption of FRUIT UP® compared with a reference food, rather than the long-term reduction of post-prandial blood glucose responses and that, therefore, this study was no longer pertinent. At that time, the applicant also submitted one additional study (Henry et al., 2007c, unpublished, claimed as proprietary by the applicant), which, according to the applicant, "has been conducted with high amounts of FRUIT UP® (171 g, corresponding to 120 g dry matter, and providing 12 g of pinitol) and had been excluded from the initial application due to this reason". In the study, seven subjects consumed either FRUIT UP® (171 g, providing 13.2 g glucose, 11.4 g fructose, 41.8 g sucrose and 12 g pinitol) or a deionised apple juice (14.5 g glucose, 28.6 g fructose and 6.6 g sucrose) three times per day. Interstitial glucose was measured every five minutes over 24 hours by means of a continuous glucose monitoring system. No analysis was provided on post-prandial blood glucose responses. The Panel notes that no analysis of post-prandial glycaemic responses was provided. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The remaining 15 human studies (all randomised, controlled cross-over trials) assessed post-prandial blood glucose responses after the consumption of FRUIT UP® or FRUIT UP®-based drinks compared with glucose (14 studies) or compared with sucrose (one study). In two of these studies, post-prandial insulinaemic responses were also assessed.

Compared with glucose, the consumption of FRUIT UP® (Henry et al., 2005, 2007a, b, 2008a, b; Sydney University, 2008) and FRUIT UP®-based drinks (Henry et al., 2008c, d, e, 2009a, b, 2010a, b; Thondre and Lightowler, 2012) significantly decreased post-prandial blood glucose responses. This effect was not observed when FRUIT UP® was compared with sucrose (Hernández-Mijares et al., 2013).

Post-prandial insulinaemic responses were shown not to be increased following consumption of FRUIT UP® compared with the reference foods, i.e. glucose and sucrose, respectively (Henry et al., 2009b; Hernández-Mijares et al., 2013).

The Panel notes that post-prandial glycaemic responses following consumption of fructose are about 20 % lower than the post-prandial glycaemic responses following consumption of the same amounts of glucose. Considering that sucrose is a disaccharide of glucose and fructose, the significantly lower post-prandial glycaemic responses observed with the consumption of FRUIT UP® and FRUIT UP®-based beverages, compared with pure glucose, could be explained by the partial replacement of glucose with fructose in FRUIT UP®. The Panel also notes that the only study which compared FRUIT UP® with similar amounts of sugars from sucrose (contains a similar proportion of glucose and fructose as found in FRUIT UP®) did not show a significant effect of FRUIT UP® on post-prandial glycaemic responses (compared with sucrose). Therefore, the applicant was informed by EFSA that a claim on fructose as compared with glucose or sucrose and a reduction of post-prandial blood glucose responses had already been evaluated with a favourable outcome (EFSA NDA Panel, 2011).

In reply, the applicant claimed that the effect of FRUIT UP® on post-prandial blood glucose responses observed in the studies using glucose as the comparator could not only be explained by a partial replacement of glucose with fructose, but were also likely to be caused by the presence of various "bio-active" substances, in particular pinitol and myo-inositol, in FRUIT UP®. The applicant also claimed that FRUIT UP® decreased post-prandial blood glucose responses compared with sucrose in the only study (Hernández-Mijares et al., 2013) available. The Panel notes that the only study available comparing FRUIT UP® with sucrose did not find significant differences in the post-prandial blood glucose responses. The Panel also notes that none of the studies which compared FRUIT UP® with glucose provides information on an independent effect of the so-claimed "bio-active" substances in FRUIT UP® on the reduction of post-prandial blood glucose responses (i.e. on an effect of FRUIT UP® over and above the effect which could be expected from the partial replacement of glucose with fructose).

The Panel notes that, in the absence of evidence for an effect of FRUIT UP® on a reduction of post-prandial blood glucose responses beyond which could be expected by the partial replacement of glucose with fructose in humans, animal studies on other potential mechanisms were not considered by the Panel for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that in the human intervention studies, from which conclusions could be drawn, FRUIT UP® decreased post-prandial blood glucose responses compared with glucose but not compared with sucrose, and that this effect may be explained by the partial replacement of glucose with fructose.

The Panel concludes that a cause and effect relationship has not been established between the consumption of FRUIT UP® and a reduction of post-prandial glycaemic responses over and above the well-established effect of fructose on reducing post-prandial glycaemic responses when replacing glucose in foods.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, FRUIT UP®, which is the subject of the health claim, and the food (i.e. glucose, sucrose) which FRUIT UP® should replace in foods or beverages, are sufficiently characterised in relation to the claimed effect.

- The claimed effect proposed by the applicant is the "reduction of post-prandial blood glucose responses". The target population proposed by the applicant is: "individuals from the general population wishing to reduce their post-prandial glycaemic responses". A reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of FRUIT UP® and a reduction of post-prandial glycaemic responses over and above the well-established effect of fructose on reducing post-prandial glycaemic responses when replacing glucose in foods.

DOCUMENTATION PROVIDED TO EFSA

1. Health claim application on FRUIT UP® and reduction of post-prandial blood glucose responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (EFSA-Q-2014-00405, Claim serial No: 0418_ES). June 2014. Submitted by WILD-Valencia SAU.

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